

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

DMB
Display Date 4-26-02
Publication Date 4-28-02
Certifier N. Hawkins

[Docket No. 97P-0210]

**Medical Devices; Ear, Nose and Throat Devices; Reclassification of the
Endolymphatic Shunt Tube With Valve**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

0356 02 APR 25 13:30

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the endolymphatic shunt tube with valve from class III (premarket approval) into class II (special controls). The device is intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of Meniere's disease. FDA is also identifying the guidance document entitled "Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve; Guidance for Industry and FDA" (the guidance) as the special control that the agency believes will reasonably ensure the safety and effectiveness of the device. This reclassification is based on new information submitted in a reclassification petition by E. Benson Hood Laboratories, Inc. (Hood Laboratories). FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the guidance.

DATES: This rule is effective [*insert date 30 days after date of publication in the Federal Register*].

ch0168

NFR 1

FOR FURTHER INFORMATION CONTACT: Eric Mann, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 15, 2001 (66 FR 42809), FDA published a proposed rule to reclassify the endolymphatic shunt tube with valve from class III (premarket approval) into class II (special controls) based on new information regarding this device. FDA also identified the document entitled “Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve; Guidance for Industry and FDA” as the special control capable of providing reasonable assurance of safety and effectiveness for this device.

Interested persons were invited to comment on the proposed rule by November 13, 2001. FDA received one comment. The comment, from the petitioner, Hood Laboratories, supported the proposed reclassification.

II. FDA’s Conclusion

Based on a review of the available information referenced in the preamble to the proposed rule and placed on file in FDA’s Dockets Management Branch, FDA concludes that the guidance document entitled “Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve; Guidance for Industry and FDA,” in conjunction with general controls, provides reasonable assurance of the safety and effectiveness of this device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the endolymphatic shunt tube with valve from class III will relieve all manufacturers of these devices of the cost of complying with the premarket approval requirements in section 515 of the act.

FDA believes that Hood Laboratories is the only manufacturer of the endolymphatic shunt tube with valve and Hood Laboratories states that they are in compliance with special controls proposed for this device. Therefore, the special controls will not impose significant new costs on the affected manufacturer. Because reclassification will reduce regulatory costs with respect to the endolymphatic shunt tube with valve, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR part 874 continues to read as follows:

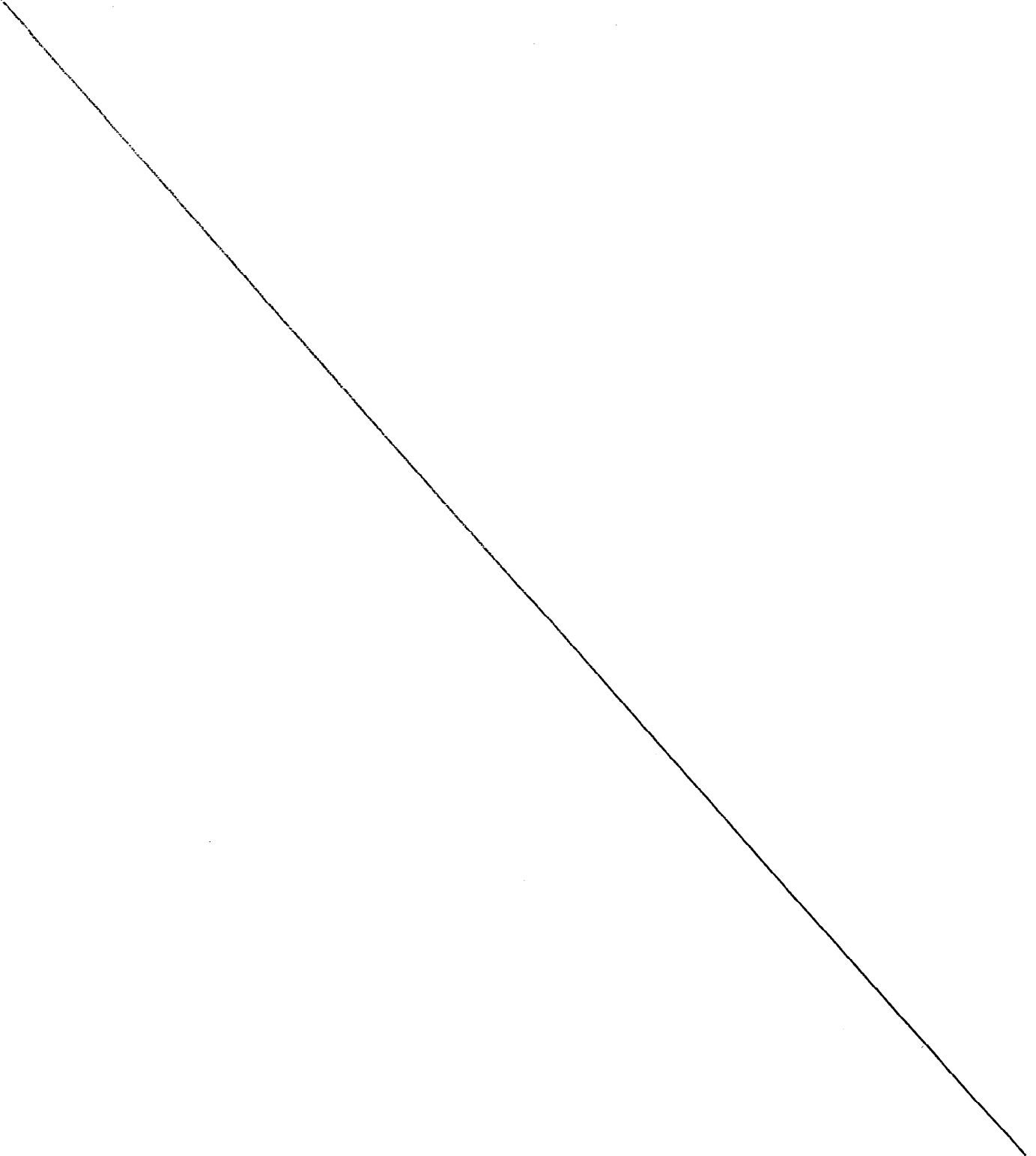
Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 874.3850 is revised to read as follows:

§ 874.3850 Endolymphatic shunt tube with valve.

(a) *Identification.* An endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve

symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of Meniere's disease.



(b) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document "Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve; Guidance for Industry and FDA."

Dated: 4/15/02

April 15, 2002.



Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

